JUN 1 3 2010 K092194

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 06/04/10

1. Company making the submission

	Submitter
Name	Kyungwon Medical Co.,Ltd
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Contact	Ju Yun
Website	http://www.kyungwonmedical.com

2. U.S Agent/Contact Person

13340 E Firestone Blvd. Suite J,
Santa Fe Springs, CA 90670
Joyce Bang
Phone: 562-404-8466 Fax: 562-404-2757
Email : kodentinc@gmail.com

3. Device

Trade Name: PolyBone® Dental
Common Name: Bone Grafting Material
Classification Name: Bone Grafting Material, Synthetic
Classification regulation: 21CFR872.3930

2. Predicate Device:

OSSAPLAST™ DENTAL(K053374) / Cerasorb® M Dental(K051443)

3. Description:

PolyBone® Dental is a synthetic resorbable calcium phosphate bone grafting material which consists of 100% beta-tricalcium phosphate.
It is an osteoconductive material which provides a porous scaffold upon which bone formation can occur. The multidirectional interconnected porosity ranges from 75~85% with a 200~500 μm pore size.
Mechanism of PolyBone Dental's bone regeneration works by bone cells resorbing dicalciumphosphate dihydrate (DCPD, brushite), which is a conversion material of β tricalcium phosphate.

4. Indication for use:

PolyBone® Dnetal is indicated to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. It is specifically for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral, maxillofacial and dental intraosseous defects including: ridge augmentation; sinus lifts; craniofacial augmentation; filling of defects of endodontic origin; filing of cystic defects; filling of extraction site; filling of lesions of periodontal origin; repair of traumatic defects of the alveolar ridge; filling resection defects in bone tumors; cysts or other osseous defects; and substitute for autogenous of allergenic bone grafts. PolyBone® Dental is a bone graft substitute that resorbs and it is replaced with bone during the healing process.

5. Review:

PolyBone® Dental has the similar technological characteristics to the predicate devices: components, indication for use, chemical and performance properties.

Components Similarities
All devices are packed in containers.

Indication for Use Similarities
All devices have the same indication for use.

Chemical Similarities
All devices are made up from β-Tricalcium phosphate family.

Performance Properties Similarities
All devices are for filling, augmenting, or reconstructing periodontal or bony defects or the oral, maxillofacial region.

Biocompatibility
The biocompatibility test of PolyBone® Dental has been performed based on ISO10993-1:2003; cytotoxicity, sensitization, irritation, intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity and implantation. The testing results show PolyBone® Dental to be biologically safe.

6. Conclusion

Based on the information provided in this premarket notification, Kyungwon Medical Co.,Ltd. concludes that PolyBone® Dental is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 1 3 2010

Kyungwon Medical Company, Limited
C/O Ms. Joyce Bang
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K092194
Trade/Device Name: Polybone® Dental
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: June 4, 2010
Received: June 7, 2010

Dear Ms. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known) K092194

Device Name: PolyBone® Dental

Indications for Use:

PolyBone® Dental is indicated to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. It is specifically for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral, maxillofacial and dental intraosseous defects including: ridge augmentation; sinus lifts; craniofacial augmentation; filling of defects of endodontic origin; filing of cystic defects; filling of extraction site; filling of lesions of periodontal origin; repair of traumatic defects of the alveolar ridge; filling resection defects in bone tumors; cysts or other osseous defects; and substitute for autogenous of allergenic bone grafts. PolyBone® Dental is a bone graft substitute that resorbs and it is replaced with bone during the healing process.

Prescription Use X AND/OR Over-The-Counter Use
(21CRF 801 Subpart D) (21CRF 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mby for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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